REMARKS

Claims 89-102 remain in the application. Claim 89 is amended to emphasize distinctions over cited art, as discussed in greater detail below.

Claims 89-101 are rejected under 35 USC 103(a) as being unpatentable over US 2002/0177843 (hereinafter "Anderson") in view of 5,713,831 (hereinafter "Olsson").

Anderson discloses a robotic surgical tool with ultrasound cauterizing and cutting instrument. A surgical instrument for enhancing robotic surgery generally includes an elongate shaft with an ultrasound probe, an end effector at the distal end of the shaft, and a base at the proximal end of the shaft. The end effector includes an ultrasound probe tip and the surgical instrument is generally configured for convenient positioning of the probe tip within a surgical site by a robotic surgical system. Ultrasound energy delivered by the probe tip may be used to cut, cauterize, or achieve various other desired effects on tissue at a surgical site. In various embodiments, the end effector also includes a gripper, for gripping tissue in cooperation with the ultrasound probe tip. The base is generally configured to removably couple the surgical instrument to a robotic surgical system and to transmit forces from the surgical system to the end effector, through the elongate shaft. A method for enhancing robotic surgery generally includes coupling the surgical instrument to a robotic surgical system, positioning the probe tip in contact with tissue at a surgical site, and delivering ultrasound energy to the tissue.

Olsson discloses a method and apparatus for arterial reperfusion through non-invasive ultrasonic action which transforms supplied energy into ultrasound signals and transmits the ultrasound signals into a body sufficiently to influence the dissolution of thrombus in a blood vessel in the body. A transducer for the transmitting has piezoelectric crystals, the crystals respectively sending the ultrasound signals each with a defined energy level and at least one frequency in an individual direction non-simultaneously with any other of the crystals.

Applicants' claim 89, as amended, recites:

> 89. Invasive or minimally invasive apparatus for removal, breakdown or erosion of undesirable deposits present on, at or in actuating bodily implants or actuating bodily-members or organs of a patient comprising:

at least one distal acoustic emitter capable of directing acoustic energy toward a target bearing said deposits for the purpose of removing at least some of said deposit and recovering a desired degree of actuation;

an exciter to power and control the emitters acoustic operation;

the distal emitter including a deformable or soft standoff, protective member or appendage, the standoff at least one of (i) preventing or inhibiting direct emitter-target contact, (ii) allowing for gentle stoppage or suppression of the targets actuation for deposit removal, and (iii) allowing for passage of the emitter into or through the actuator without damaging the actuator;

a proximally grippable scope, catheter, handle, guidewire, sheath or a gripping robot distally supporting the emitter and allowing a practitioner to control acoustic coupling of and use of the emitter on the target;

wherein by actuating is specifically meant that the implant or body member being treated for deposit has (a) adjacent, joined or mating portions which normally at least one of swing, hinge, pivot, distend, or flex relative to each other at least once or (b) mating parts which are plugged, connected, threaded or passed into or through each other at least once; and

said deposit either currently negatively impacts normal actuation or threatens to worsen such that it eventually degrades actuation, thereby negatively impacting the patient.

Applicants claim an apparatus for recovering the normal full motions or actuations of bodily parts such as the cyclic hinging angulation of unfouled heart valves. Examiner points out that Anderson has taught actuating parts. However, Anderson's actuating parts are all part of his robot or robot-held tools and NOT anatomical parts. Examiner states that Anderson teaches recovery of the actuation of anatomical parts, such as dysfunction due to fouling or thrombus deposits for example. With all due respect, that simply is not the case.

Specifically, Anderson never even uses the word *deposit* or *deposits*, never uses the word *clean* or *cleans*, never uses the words *thrombus*, *calcification*, *stuck* or *sticking*, never uses the words *foul*, *fouled* or *fouling*, never uses the words *plaque* or *plaques*, never uses the words *block* or *blockage*, never uses the word *remove*, *removes* or *removal* with respect to such deposits/growths but only with respect to removable robot parts, never mentions *valves to be defouled* or *cleaned*, never mentions *implants to be defouled* or *cleaned* and finally, in mentioning *motion* or *articula-*

tion does so only with respect to his moving robot parts. And while it is recognized that a reference does not have to use the same words as Applicants do, nevertheless, the reference should teach or suggest the same invention as claimed by Applicants. Here, Anderson does not teach anything approximating Applicants' claimed invention.

Thus, Anderson teaches a robot apparatus with moving parts and teaches nothing about moving or actuating anatomy nor correcting or recovering such anatomic movement or actuation using any tool including his robot, nor doing so with an ultrasonic emitter which includes a tissue protective standoff.

Anderson mentions *cauterization*, which is a blood vessel sealing process and not a deposit or foulant removal process. Cutting scalpels, including robotic scalpels, would be expected to cauterize their cuts. However, this has no bearing on Applicants' claimed invention.

The Examiner states that Anderson discusses actuation of bodily parts in his paragraph 0100. In fact, he is discussing his actuating robot parts and is not discussing normally moving or actuating anatomy.

Looking now at Olsson, we begin by noting that Olsson specifically addresses reperfusion of clogged lumens and Applicants have explicitly excluded lumens as actuating anatomy because there are no parts of healthy lumens which hinge, pivot or slide (with the exception of peripheral valves in leg lumens which are taught exclusively by Applicants and have hinged actuating parts similar to heart valves).

Olsson's teaching with respect to deposits or thrombus is exclusively addressed to clogged lumens which are logically excluded from our invention as having no actuation even when healthy. Neither Olsson nor Anderson teaches or suggests recovery of healthy anatomic actuation of body parts or implants as Applicants do. This is further demonstrated by the fact that Olsson never mentions words such as *valves*, *motion* or *movement*, *actuate* or *actuation*, *stuck* or *stick*.

The Examiner also contends that Olsson's external noninvasive transducer would lead one to apply a similar standoff to Applicants' device via modification of Anderson's ultrasonic robot tool. With all due respect, this is simply not the case. In ultrasound, a standoff is widely known to be a low-loss material body introduced to increase an acoustic path length or to otherwise improve acoustic coupling to a tar-

get and which is placed between emitter and tissue. Olsson introduces no such standoff and in fact states that his emitters are placed directly against tissue, thus teaching away from Applicants' invention as claimed. The Examiner contends that the skin is a standoff for Olsson's device, but Applicants' claimed invention cannot be operated through the skin as it comprises an invasive or minimally invasive device with a distal emitter. Further, Applicants teach the standoff being soft or deformable such as to allow damage-free contact or gentle forceful passage through a fouled valve. Skin, which is not available **in the vicinity of** a fouled valve, does not allow Olsson such close-proximity contact nor passage. Skin is not of low acoustic loss either as is Applicants' preferred saline-balloon standoff. Thus, Anderson and Olsson, alone or in combination, fail to disclose or suggest any invasive device with a soft or deformable standoff, or one which is integral to the emitter or one having low acoustic loss. Supportive of this is the fact that Olsson and Anderson never mention the words *balloon*, *soft* or *standoff* as neither discusses contacting or passing through a valve, for example.

The amended language in independent claim 89, namely, "the distal emitter including a deformable or soft standoff, protective member or appendage", makes it explicitly clear that skin cannot serve the purposes taught for the standoff.

Reconsideration of the rejection of claims 89-101, as amended, under 35 USC 103(a) as being unpatentable over Anderson in view of Olsson is respectfully reted.

Applicants appreciate that claim 102 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, Applicants submit that the foregoing arguments and amendments to claim 89 render the remaining claims allowable.

The foregoing amendments and arguments are submitted to place the application in condition for allowance. The Examiner is respectfully requested to take such action. If the Examiner has any questions, she is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,

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